

We Claim:

1. A sustained release oral dosage form comprising:
a single functional layer; and
optionally, one or more nonfunctional layers adjacent to the single functional layer,
wherein the single functional layer comprises alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof and one or more release retarding ingredients.
2. The sustained release oral dosage form of claim 1, wherein the release retarding ingredient comprises one or more of cellulose polymer, methacrylate polymer, acrylic acid polymer, block copolymer, gum and polyethylene oxide.
3. The sustained release oral dosage form of claim 2, wherein the cellulose polymer comprises one or more of hydroxypropyl methylcellulose, methylcellulose, hydroxypropylethylcellulose and hydroxypropyl cellulose.
4. The sustained release oral dosage form of claim 2, wherein the gum comprises one or more of xanthan gum, alginic acid, sodium alginate and locust bean gum.
5. The sustained release dosage form of claim 1, wherein the single functional layer further comprises one or more pharmaceutically acceptable excipients.
6. The sustained release oral dosage form of claim 1, wherein the one or more pharmaceutically acceptable excipients comprise one or more of binders, diluents, and lubricants/glidants.
7. The sustained release oral dosage form of claim 6, wherein the binders comprise one or more of polyvinyl pyrrolidone, pregelatinized starch, and gelatin.
8. The sustained release oral dosage form of claim 6, wherein the diluents comprise one or more of lactose, mannitol, and microcrystalline cellulose.

9. The sustained release oral dosage form of claim 6, wherein the lubricants comprise one or more of magnesium stearate, zinc stearate, talc, and colloidal silicon dioxide.

10. The sustained release oral dosage form of claim 1, wherein the functional layer comprises between about 10% to about 90% w/w of hydroxypropyl methylcellulose and between about 10% to about 90% w/w of hydroxypropyl cellulose.

11. The sustained release oral dosage form of claim 1, wherein the functional layer comprises between about 10% to about 70% w/w of hydroxypropyl methylcellulose, between about 10% to about 70% w/w of hydroxypropyl cellulose and between about 1% to about 20% w/w of methacrylic acid copolymer.

12. The sustained release oral dosage form of claim 1, wherein the functional layer comprises between about 10% to about 70% w/w of hydroxypropyl methylcellulose, between about 10% to about 70% w/w of hydroxypropyl cellulose, between about 5% to about 10% w/w of methacrylic acid copolymer, and between about 10% to about 50% w/w of lactose.

13. The sustained release dosage form of claim 1, wherein the dosage form comprises one or more of tablets, capsules, pellets, granules and other dosage forms suitable for oral administration.

14. The sustained release oral dosage form of claim 1, wherein the dosage form has a dissolution of less than about 17% in about 1 hour, less than about 61% in about 8 hours, less than about 94% in about 20 hours, as measured in a pH 6.8 phosphate buffer using USP Type II apparatus with a paddle speed of 100 rpm, at 37 ± 2 °C.

15. The sustained release oral dosage form of claim 1, wherein the dosage form has a dissolution of less than about 26% in about 2 hours, less than about 77% in about 12

hours, and less than about 96% in about 24 hours, as measured in a pH 6.8 phosphate buffer using USP Type II apparatus with a paddle speed of 100 rpm, at 37 ± 2 °C.

16. The sustained release oral dosage form of claim 1, wherein the dosage form has a dissolution of less than about 39% in about 4 hours and less than about 88% in about 16 hours, as measured in a pH 6.8 phosphate buffer using USP Type II apparatus with a paddle speed of 100 rpm, at 37 ± 2 °C.

17. The sustained release oral dosage form of claim 1, wherein the single functional layer comprises granules.

18. The sustained release oral dosage form of claim 1, wherein the one or more nonfunctional layers adjacent to the single functional layer comprises a cosmetic coating.

19. The sustained release oral dosage form of claim 18, wherein the cosmetic coating comprises a colorant.

20. A method of treating secondary symptoms associated with benign prostatic hyperplasia, the method of treating comprising administering a sustained release oral dosage form, the sustained release oral dosage form comprising a single functional layer and, optionally, one or more nonfunctional layers adjacent to the single functional layer, wherein the single functional layer comprises alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof and one or more release retarding ingredients.

21. The method of claim 20, wherein the release retarding ingredient comprises one or more of cellulose polymer, methacrylate polymer, acrylic acid polymer, block copolymer, gum and polyethylene oxide.

22. The method of claim 21, wherein the cellulose polymer comprises one or more of hydroxypropyl methylcellulose, methylcellulose, hydroxypropylethylcellulose and hydroxypropyl cellulose.

23. The method of claim 21, wherein the gum comprises one or more of xanthan gum, alginic acid, sodium alginate and locust bean gum.
24. The method of claim 20, wherein the sustained release oral dosage form is administered twice daily.
25. The method of claim 20, wherein the sustained release oral dosage form is administered once daily.
26. The method of claim 20, wherein the single functional layer comprises granules.
27. The method of claim 20, wherein the one or more nonfunctional layers adjacent to the single functional layer comprise a cosmetic coating.
28. The method of claim 27, wherein the cosmetic coating comprises a colorant.
29. A process for forming a sustained release oral dosage form, the process comprising:
forming a mixture of alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof and one or more release retarding ingredients;
forming a dosage form having a single functional layer from the mixture; and
optionally forming one or more nonfunctional layers adjacent to the single functional layer.
30. The process of claim 29, wherein the release retarding ingredient comprises one or more of cellulose polymer, methacrylate polymer, acrylic acid polymer, block copolymer, gum and polyethylene oxide.
31. The process of claim 30, wherein the cellulose polymer comprises one or more of hydroxypropyl methylcellulose, methylcellulose, hydroxypropyl ethylcellulose and hydroxypropyl cellulose.

32. The process of claim 30, wherein the gum comprises one or more of xanthan gum, alginic acid, sodium alginate and locust bean gum.
33. The process of claim 29, wherein the one or more nonfunctional layers adjacent to the single functional layer comprise a cosmetic coating.
34. The process of claim 33, wherein the cosmetic coating comprises a colorant.
35. The process of claim 29, wherein forming a mixture comprises one or more of direct compression, wet granulation, and dry granulation.
36. The process of claim 29, wherein forming a mixture comprises forming granules that comprise the alfuzosin or pharmaceutically acceptable salt, solvate, enantiomers or mixtures thereof and one or more release retarding ingredients.
37. The process of claim 29, wherein forming a mixture further comprises adding one or more pharmaceutically acceptable excipients to the mixture.
38. The process of claim 29, wherein forming the dosage form having a single functional layer comprises one or more of forming tablets, capsules, pellets, granules or other dosage form suitable for oral administration.
39. The process of claim 38, wherein forming the dosage form further comprises compressing to form a tablet.
40. The process of claim 38, wherein forming the dosage form further comprises filling into a capsule.